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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/723,189

11/27/00

BENNER

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EXAMINER

HM12/0523

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ART UNIT

PAPER NUMBER

1619

DATE MAILED:

05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/723,189

Applicant(s)

BENNER ET AL.

Examiner

Mina Haghighatian

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: A brief description of drawings is required in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite due to "chosen from the group of emulsifiers having the following properties". Must emulsifier A have all of the "following properties" or does it need to meet just one of the conditions? Claim 1 is vague and indefinite due to "and/or". Only one conjugate should be selected. Claim 1 is vague and indefinite because of "also optionally further substances". The term "also" can be excluded and the term "comprising" can be added after "further". The terms "including", "preferably" and "in particular" are limitations within limitations and can not be in the same claim. The term "primarily" is vague and indefinite. The term "an effective amount" is vague and indefinite. What is this effective to do?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Richard et al (5,900,231).

Richard teaches compositions for topical applications useful as desquamating and/or anti-aging formulations, containing karite oil, emulsifiers and other optional additives. The composition may be in the form of emulsions, oil-in-water or water-in-oil, or microemulsions, and the emulsifier portion can be ranging from 0.3 to 30% and preferably from 0.5 to 20% by weight relative to the total weight of the composition. Examples of these emulsifiers are sorbitan stearate and polysorbate 60, (see columns 8-9). The concentration of karite oil is 7% in the composition example, which meets the range required in the instant claim 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zabotto et al (4,661,343) in view of Gohla et al (5,750,124).

Zabotto teaches a cosmetic preparation containing karite oil, which is derived from karite butter, also known as shea butter. He discloses that emulsions of the type water-in-oil or oil-in-water can be prepared which contains an emulsifying agent from 1 to 20 %, and preferably from 2 to 12 %, by weight, and karite oil from 2 to 30 % by weight of the emulsion, (see col.4, lines 22-27 and col.3, lines 25-26). Zabotto lacks teachings on specific properties of the emulsifier.

Gohla teaches multiple emulsions comprising at least one emulsifier whose lipophilicity increases with increasing temperature and hydrophilicity of which increases with decreasing temperature, the emulsifiers changing from an HLB value <10 to an HLB value of >10 in the temperature range of 40-90 degrees centigrade, the HLB value of the emulsifier or emulsifiers at room temperature being between 11 and 18, the emulsifier not being completely soluble in the oily phase; also optionally further auxiliaries and/or additives to stabilize the multiple emulsion droplets; and other

additives and/or active compounds customary in cosmetics or medical preparations, (see abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the composition of Zabbotto, an emulsion containing shea butter, by using the teachings of Gohla on the emulsions containing emulsifiers with such specific properties, because of the expectancy of producing composition systems which are stable microscopically over relatively long storage times or in a wide temperature range or towards extreme variations in temperature.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zabotto et al and Gohla et al as applied to claims 1-3 and 6-9 above, and further in view of Muller et al (4,719,239).

Zabotto and Gohla's teachings were discussed above.

Muller teaches pharmaceutical multicomponent systems and method of preparing them. He teaches that macroemulsions form at room temperature and microemulsions form at higher temperatures, and that traditional macroemulsions and microemulsions were lacking stability and therefore were not suitable carriers. Muller then, discloses that the nature and concentration of the coemulsifiers of the surfactant and cosurfactant determine both the scope of the thermodynamic, stable, single-phase range and also the viscosity of the system and the temperature range in which there is thermodynamic stability.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the composition of the combined references of an

emulsion containing shea butter and emulsifiers with specific properties, by using the teachings of Muller on macroemulsions and microemulsions systems, because of the expectancy to produce an emulsion system which is both stable and convertible, and would ultimately perform better as a cosmetic and/or pharmaceutical carrier.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure, Breton et al (6,224,850 B1) and Menzel et al (5,993,857).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghghatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

May 17, 2001


**DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

Mina Haghghatian
Patent Examiner
Art Unit 1619